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Long-term Outcomes after Angioplasty of Isolated, Below-the-knee Arteries in Diabetic Patients with Critical Limb Ischaemia

Ferraresi R., Centola M., Ferlini M., Da Ros R., Caravaggi C., Assaloni R., Sganzaroli A., Pomidossi G., Bonanomi C., Danzi G.B. Eur J Vasc Endovasc Surg 2009;xx:xx-xx.

Background: It has been shown that concomitant percutaneous transluminal angioplasty (PTA) of above-the-knee (ATK) and below-the-knee (BTK) arteries is highly beneficial for limb salvage in patients with critical limb ischaemia (CLI), but few published studies have specifically investigated outcomes in diabetic patients with CLI associated with isolated small BTK-vessel disease. This study aimed to evaluate the long-term results of successful PTA for limb salvage in such patients.

Materials and methods: From among the 634 patients with CLI in our database, we retrospectively selected a consecutive series of 101 diabetics (16%) with 107 critically ischaemic limbs (33 Rutherford 5 and 74 Rutherford 6) and no critical ATK lesion, who underwent PTA on isolated BTK lesions.

Results: The limb salvage rate was 93% after a mean follow-up of 1048 ± 525 days (2.9 ± 1.4 years). Transcutaneous oxygen tension significantly increased after 1 month (18.1 ± 11.2 vs. 39.6 ± 15.1; $p < 0.05$). After 1 year, target-vessel re-stenosis had occurred in 42% of the non-amputated limbs, nine patients (9%) had died because of medical conditions unrelated to PTA and three patients had undergone repeat PTA for recurrent CLI.

Conclusions: In our selected patient population with ischaemic diabetic foot and isolated BTK lesions, a successful endovascular procedure led to a high percentage of limb salvage at long-term follow-up.

A Randomised Open-Label Trial Comparing Long-term Sub-Cutaneous Low-Molecular-weight Heparin Compared with Oral-Anticoagulant Therapy in the Treatment of Deep Venous Thrombosis

Romera A., Cairols M.A., Vila-Coll R., Martí X., Colomé E., Bonell A., Lapiedra O. Eur J Vasc Endovasc Surg 2009;xx:xx-xx.

Objective: To evaluate whether low-molecular-weight heparin (LMWH) could be equally (or more) effective than oral anti-vitamin-K agents (AVK) in the long-term treatment of deep venous thrombosis (DVT).

Design: A randomised, open-label trial.

Material and methods: In this trial, 241 patients with symptomatic proximal DVT of the lower limbs confirmed by duplex ultrasound scan were included. After initial LMWH, patients received 6 months of treatment with full therapeutic dosage of tinzaparin or acenocoumarol. The primary outcome was the 12-month incidence of symptomatic recurrent venous thrombo-embolism (VTE). Duplex scans were performed at 6 and 12 months.

Results: During the 12-month period, six patients (5%) of 119 who received LMWH and 13 (10.7%) of 122 who received AVK had recurrent VTE ($p = 0.11$). In patients with cancer, recurrent VTE tended to be lower in the LMWH group (two of 36 [5.5%]) vs. seven of 33 [21.2%]; $p = 0.06$). One major bleeding occurred in the LMWH group and three in the AVK group. Venous re-canalisation increased significantly at 6 months (73.1% vs. 47.5%) and at 12 months (91.5% vs. 69.2%) in the LMWH group.

Conclusions: Tinzaparin was more effective than AVK in achieving re-canalisation of leg thrombi. Long-term tinzaparin was at least as efficacious and safe as AVK for preventing recurrent VTE, especially in patients with cancer.

Randomised Comparison of Costs and Cost-Effectiveness of Cryostripping and Endovenous Laser Ablation for Varicose Veins: 2-Year Results

Disselhoff B.C.V.M., Buskens E., Kelder J.C., der Kinderen D.J., Moll F.L. Eur J Vasc Endovasc Surg 2009;xx:xx-xx.

Background: Although endovenous laser ablation for varicose veins is replacing surgical stripping, proper economic evaluation with adequate follow-up in a randomised clinical trial is important for considered policy decisions regarding the implementation of new techniques.

Methods: Data from a randomised controlled trial comparing cryostripping and endovenous laser ablation in 120 patients were combined to study Short Form (SF) 6D outcome, costs and cost-effectiveness 2 years after treatment. Incremental cost per quality-adjusted life year (QALY) gained 2 years after treatment was calculated using different strategies, and uncertainty was assessed with bootstrapping.

Results: Over the total study period, mean SF-6D scores improved slightly from 0.78 at baseline to 0.80 at 2 years for patients who underwent cryostripping and from 0.77 to 0.79 for patients who underwent endovenous laser. QALY (SF-6D) was 1.59 in patients who underwent cryostripping and 1.60 in patients who underwent endovenous laser 2 years after treatment. The costs of cryostripping and endovenous laser per patient were €2651 and €2783, respectively. Bootstrapping indicated that cryostripping was associated with an incremental cost-effectiveness ratio of €32 per QALY gained. With regard to different strategies, outpatient cryostripping was less costly and more effective 2 years after treatment.

Conclusion: In this study, in terms of costs per QALY gained, outpatient cryostripping appeared to be the dominant strategy, but endovenous laser yielded comparable outcomes for a relatively little additional cost.